No. 98-1152

IN THE
Supreme Court of the United States

FOOD and DRUG ADMINISTRATION, *et al.*,
Petitioners,
v.
BROWN and WILLIAMSON TOBACCO CORP., *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

BRIEF FOR RESPONDENTS NATIONAL ASSOCIATION OF CONVENIENCE STORES AND ACME RETAIL, INC.

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QUESTION PRESENTED

Whether Congress granted jurisdiction to the Food and Drug Administration to regulate the retail sale of tobacco products under the medical device provisions of the Federal Food, Drug, and Cosmetic Act, even though Congress expressly proscribed any regulation inconsistent with state autonomy preserved by the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act.

RULE 29.6 LISTING

There is no parent or subsidiary company to be listed pursuant to Rule 29.6.

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OPINIONS BELOW

The opinions below are identified in Brief for Petitioners (Pet. Br.) 1.

JURISDICTION

The basis for this Court's jurisdiction is set forth at Pet. Br. 1.

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The Brief for Petitioners fails to list among the statutes involved the ADAMHA Reorganization Act.

STATEMENT

From the time tobacco products were first marketed in this country, their retail sale has been regulated by the States (and local governments), and not by the national government. Congress, in 1992, recognized and expressly preserved local autonomy over tobacco retailing in the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act (the "ADAMHA Amendments").

In 1996, claiming jurisdiction under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Secretary of Health and Human Services ("HHS") and the Commissioner of Food and Drugs declared the end of state autonomy in tobacco-access control by promulgating regulations prescribing how cigarettes and smokeless tobacco could be distributed and sold throughout the United States. 61 Fed. Reg. 44,396 (1996). These regulations, to be enforced by the Food and Drug Administration ("FDA"), prohibit the sale of cigarettes and smokeless tobacco to those under age 18, and require retailers to check identification of persons under age 27, 21 C.F.R. § 897.14(a)-(b) (1999); prohibit vending machine sales except in adult-only establishments, *id.* § 897.16(c)(2)(ii); prohibit self-service displays of tobacco products, *id.* § 897.16(c)(1); and prohibit the provision of free samples to any person, *id.* § 897.16(d).

The regulations extend FDA's enforcement responsibilities to over 500,000 retail establishments throughout the United States. 61 Fed. Reg. 44,578. Retailers of tobacco products, including 68,000 outlets operated by members of respondent, National Association of Convenience Stores, must redesign and reconstruct their stores to comply with the regulations. 61 Fed. Reg. 44,589. Every failure to conform to FDA's mandate is a federal offense, 21 C.F.R. § 897.1(b); 21 U.S.C. §§ 331(b), (k), punishable by federal prosecution, *id.* § 333(a)(1), or by civil penalty imposed by FDA and reviewable in the federal courts of appeals, *id.* § 333(f). Respondents brought suit challenging FDA's assertion of jurisdiction under the FDCA.

SUMMARY OF ARGUMENT

Historically, state and local governments decided how to regulate the retail sale of tobacco in the United States. Such laws have ranged from complete bans (since repealed) on cigarette sales at the turn of the century to restrictions on sales to minors, self-service displays, vending machines, or free samples (which continue to the present). Against this backdrop, in July 1992, Congress passed, and the President signed, the ADAMHA Amendments, Pub. L. No. 102-321, 106 Stat. 323 (1992), the most recent expression of congressional intent concerning tobacco-access regulation. The ADAMHA Amendments promise Substance Abuse Prevention and Treatment ("SAPT") block grants to States that have laws prohibiting the sale of tobacco products to individuals under age 18 and that enforce those laws effectively. 42 U.S.C. § 300x-26 (1994).

Congress, by enacting the ADAMHA Amendments, confirmed that the States should continue to enact and enforce tobacco-access restrictions, and recognized that restrictive measures appropriate for one State or locality to reach the goal of preventing underage tobacco purchases may not be right for another. The policy Congress embraced in the Amendments was not one of uniform federal regulation; rather, Congress decided to preserve and enhance the States' role in regulating access to tobacco by leaving to each State the decision as to what legislation is needed, and by rewarding with block grants those States that enforce their laws effectively.

The States and localities responded to Congress' policy. They have implemented varied regulatory approaches depending upon what restriction, or combination of restrictions, best meets the needs of the particular State or locale. One may ban cigarette vending machines outright, whereas another may impose location, line-of-sight, or lockout device requirements. In some jurisdictions penalties apply to underage purchasers, whereas in others law enforcement targets only tobacco sellers. Some States restrict free samples, coupons, or rebate offers; others do not. By enforcing these laws to achieve the tobacco-access reductions contemplated under the Amendments, every State, so far, has qualified for the full SAPT block grant promised by Congress.

Four years after Congress decided to support state authority and encourage local regulation of retail tobacco sales, FDA effectively reversed that decision. FDA's uniform regulations preempt or nullify hundreds of state and local laws, many of which the States enacted at the behest of Congress. Moreover, FDA's regulations impermissibly impose upon the States, retroactively, additional obligations that Congress did not intend when enacting the ADAMHA Amendments. FDA's regulations contradict Congress' decision about *who* should regulate access to tobacco by minors and *how* it should be done.

FDA's regime of uniform tobacco-access standards replace the legislative and enforcement flexibility that Congress determined the States should retain. Indeed, the regulatory system Congress chose is fundamentally contrary to the federal command-and-control regulatory system FDA has imposed.

Congress never granted FDA power to supplant the state-by-state regulatory system Congress had chosen; basic principles of administrative law prohibit a federal agency

from promulgating regulations that conflict with statutory directives. In this case the conflict is clear. Congress, moreover, has expressly declared that any HHS rule or regulation "inconsistent" with the ADAMHA Amendments "shall not have any legal effect[.]" Pub. L. No. 102-321, sec. 203, § 1954(b), 106 Stat. 410. For these reasons,[1] FDA's assertion of jurisdiction, and its resulting tobacco regulations, should be struck down.

ARGUMENT

I. CONGRESS EXPLICITLY PRESERVED STATE LEGISLATIVE AND ENFORCEMENT FLEXIBILITY.

A. The ADAMHA Amendments Rely Exclusively Upon States To Attain Federal Tobacco-Access-Reduction Goals.

Controversy over the consumption of tobacco predates the founding of the republic.[2] For over a hundred years, concern about public health has led state and local governments to exercise their authority to police the retail sale of tobacco within their own borders. For example, during the late 1800's and early 1900's, 14 States passed, though they later repealed, complete bans on the sale of cigarettes.[3] Throughout this century, States have restricted

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[1] Respondents on this brief agree with, and hereby rely on, the arguments made in the briefs of the other respondents.

[2] Jacob Sullum, *For Your Own Good: The Anti-Smoking Crusade and the Tyranny of Public Health* 15-23 (1998) (describing centuries of debate over tobacco).

[3] 1907 Ark. Acts 280; 1921 Ark. Acts 490; 1921 Idaho Sess. Laws 185; 1921 Idaho Sess. Laws 262; 1905 Ind. Acts 52; 1909 Ind. Acts 28; 1896 Iowa Acts 96; 1921 Iowa Acts 203; 1909 Kan. Sess. Laws 257; 1927 Kan. Sess. Laws 171; 1909 Minn. Laws 194; 1913 Minn. Laws 580; 1905 Neb. Laws 198; 1919 Neb. Laws 180; 1895 N.D. Laws 32; 1925 N.D. Laws 106; 1901 Okla. Sess. Laws 13; 1915

the legal purchase age for tobacco products.[4] Local governments have long regulated access to tobacco products,[5] and continue to do so today, *see* pp. 15-17, *infra*.

Okla. Sess. Laws 190; 1909 S.D. Laws 142; 1917 S.D. Laws 153; 1897 Tenn. Pub. Acts 30; 1921 Tenn. Pub. Acts 5; 1921 Utah Laws 145; 1925 Utah Laws 68; 1909 Wash. Laws 249; 1911 Wash. Laws 133; 1905 Wis. Laws 82; 1915 Wis. Laws 139. *See Austin v. Tennessee*, 179 U.S. 343 (1900) (upholding 1897 statute banning cigarettes sales); *see also* Rivka Widerman, *Tobacco Is A Dirty Weed. Have We Ever Liked It? A Look At Nineteenth Century Anti-Cigarette Legislation*, 38 Loy. L. Rev. 387, 423 (1992) (concluding that the primary purpose of the earliest anti-cigarette legislation was to protect young people).

[4] 1890 Ala. Acts 785; Comp. Laws of Alaska § 4967 (1933); 1921 Ariz. Sess. Laws Ch. 63 § 1; 1929 Ark. Acts 152; 1891 Cal. Stats. 70; 1891 Colo. Sess. Laws 131; Conn. Gen. Stat. § 6283 (1930); 19 Del. Laws 783 (1894); 26 D.C. Stat. 736 (1929); 1907 Fla. Laws ch. 5716; 1889 Ga. Laws 149; 1890 Haw. Sess. Laws 62; 1921 Idaho Sess. Laws 185; 1907 Ill. Laws 265; 1913 Ind. Act 643; Iowa Code § 1553 (1935); 1933 Kan. Sess. Laws 122; 1914 Ky. Acts 104; 1900 La. Acts 98; 1909 Me. Laws 123; 1914 Md. Laws 835; 1886 Mass. Acts 72; 1909 Mich. Pub. Acts 226; 1913 Minn. Laws 580; Miss. Code. Ann. § 819 (1930); 1909 Mo. Laws 447; 1895 Mont. Laws 542; 1885 Neb. Laws 105; Nev. Comp. Laws § 10184 (1929); 1885 N.H. Laws 60; 1904 N.J. Laws 163; 1901 N.M. Laws 3; 1897 N.Y. Laws 256; 1891 N.C. Sess. Laws 276; 1925 N.D. Laws 26; Ohio Code Ann. § 12965 (Banks-Baldwin 1936); 1917 Okla. Sess. Laws 148; 1893 Or. Laws 86; 1901 Pa. Laws 323; 1896 R.I. Pub. Laws 281; S.C. Code § 255(19) (1932); 1917 S.D. Laws 153; 1921 Tenn. Pub. Acts 5; 1899 Tex. Gen. Laws 237; Utah Rev. Stat. § 93-1-12 (1933); 1937 Vt. Laws 213; 1889-90 Va. Laws 213; 1895 Wash. Laws 126; W. Va. Code Ann. Ch. 150 § 20e (Barnes 1923); 1891 Wis. Laws 434; 1895 Wyo. Sess. Laws 46.

[5] *See Gundling v. City of Chicago*, 177 U.S. 183, 187-88 (1900) ("Whether dealing in and selling cigarettes is that kind of a business which ought to be licensed is, we think, considering the character of the article sold, a question for the state, and through it, for the city, to determine for itself, and that an ordinance providing reasonable conditions upor the performance of which a

At the federal level, Congress has repeatedly considered legislation addressing who should regulate tobacco marketing and promotion, and how they should do so. An extensive body of statutory law has emerged from those deliberations and embodies Congress' intent.[6] The last expression of congressional intent on this subject, which came in the ADAMHA Amendments of 1992, dealt with access regulation. An examination of the text, history, and constitutional basis of this law confirms that FDA lacks authority to regulate tobacco products under the FDCA.

Congress relied upon and preserved the States' authority to control youth access when it passed the ADAMHA Amendments, which established financial incentives for States to regulate access successfully. Under the Amendments, a State can qualify for a full allotment of block-grant funds if it agrees to four conditions:

(1) To have in effect a law prohibiting every manufacturer, retailer, or distributor of tobacco products from selling or distributing them to anyone under age 18 [section 300x-26(a)(1)];

(2) To enforce access restrictions "in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18" [section 300x-26(b)(1)];

(3) To conduct annual, random, unannounced inspections to measure and ensure compliance [section 300x-26(b)(2)(A)];

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license may be granted to sell such article does not violate any provision of the Federal Constitution").

[6] The Brief for Respondents Philip Morris Incorporated and Lorillard Tobacco Company describes these statutes.

(4) To submit an annual report to the Secretary of HHS describing its enforcement activities, its success in reducing tobacco access to those underage, and its strategies for enforcing its access laws in the coming year [section 300x-26(b)(2)(B)].

This program thus encourages States to enact and enforce their own tobacco-access laws. States and localities have responded exactly as Congress desired by adding measures of varying design and approach to the large body of access restrictions already on the books. *See* Addendum to Supplemental Brief of Plaintiffs-Appellees National Association of Convenience Stores and Acme Retail, Inc., in the United States Court of Appeals for the Fourth Circuit ("Addendum") (six volumes) (June 27, 1997).

Congress made clear that the federal regulatory policy was to be found in the Amendments, and was not to be altered by HHS. Specifically, section 203(a) of the ADAMHA Amendments added to the Public Health Service Act new section 1954(b), which provides in pertinent part as follows:

> (b) FEDERAL ACCOUNTABILITY.—Any rule or regulation of the Department of Health and Human Services that is inconsistent with the amendments made by this Act shall not have any legal effect. . . .

106 Stat. 410.

B. Congress Rejected All Proposals to Grant HHS Any Authority to Regulate Tobacco Access.

The legislative history of the ADAMHA Amendments confirms that Congress intended to leave the States in control of tobacco-access policy. The Amendments originated in the House Committee on Energy and Commerce.

That Committee rejected proposed language for the ADAMHA Amendments that would have undermined the States' historical role in deciding how best to regulate underage access to tobacco. On November 1, 1991, Rep. Henry Waxman, Chairman of the Committee's Subcommittee on Health and the Environment, introduced the Community Mental Health and Substance Abuse Services Improvement Act of 1991, which would have revised and extended services for mental health and substance abuse administered by the Alcohol, Drug Abuse, and Mental Health Administration ("ADAMHA") and created new incentives for States to reduce tobacco sales to those under age 18. H.R. 3698, 102d Cong. (1991). When the bill was in the Energy and Commerce Committee, Rep. Waxman offered an amendment that would have withheld grant funds unless States enacted specific access restrictions strikingly similar to those FDA promulgated in its final tobacco regulations. *See* Amendment to the Committee Print of November 15, 1991 (H.R. 3698, as Reported From the Subcommittee on Health and the Environment) (Nov. 19, 1991). Rep. Waxman's proposed amendment would have deprived a State of its block grant unless the State required that tobacco vending machines be locked, controlled, or located where persons under 18 could not enter without a parent or guardian. *Id.* at 2-3. This is the kind of specific tobacco-access restriction FDA now seeks to impose as federal law and enforce throughout the United States.[7]

On March 24, 1992, however, the Commerce Committee reported the bill without Rep. Waxman's proposal.

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[7] FDA's regulations ban the use of vending machines unless "located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time." 21 C.F.R. § 897.16(c)(2)(ii).

See H.R. 3698, 102d Cong. (1992). On the House floor, Rep. Bliley, Ranking Minority Member of the Subcommittee and the Committee, explained that the underlying policy of H.R. 3698 was to avoid any measure that "reduces the flexibility of States to address the critical needs of their populations," for such a measure "takes the initiative away from local people who have the best grasp of their local environments and shifts it to Federal bureaucrats." 138 Cong. Rec. 6622 (1992).

Undeterred, Rep. Waxman pressed his proposal one more time, in the House-Senate conference on the legislation. Rep. Bliley later described why the Conference Committee rejected it:

> Again, Rep. Waxman's staff was attempting to interject proposals to broaden the Secretary's authority beyond the scope agreed to by a majority of the Subcommittee. For this reason, the proposal was rejected by the negotiators.

Comment of Rep. Thomas A. Bliley 3 (Oct. 25, 1993) (responding to HHS's Notice of proposed regulations implementing 42 U.S.C. § 300x-26, 58 Fed. Reg. 45,156 (1993)) ("Bliley Comment").[8] Rep. Waxman's proposal offered a more detailed, federally controlled program for restricting underage access to tobacco; that program was rejected. In considering and then rejecting it, the conferees from the House and the Senate held fast to the policy that

[8] The Bliley Comment also described Rep. Waxman's initial effort to broaden the Secretary's authority: the original bill had provoked "strong objections to granting the Secretary 'significant' discretionary powers that were so broad that HHS could establish any guidelines for enforcement while insisting on compliance under the threat of a loss of funds[,]" and "[i]t was generally agreed that such an enforcement scheme went beyond the establishment of a minimum age requirement and would usurp state flexibility in determining reasonable enforcement mechanisms." Bliley Comment 2.

States continue to be free to design tobacco-access restrictions unhindered by the dictates of the federal bureaucracy. This policy became the Act of Congress.

C. HHS Recognized Congressional Intent to Preserve State Autonomy.

HHS recognized congressional intent in 1996 when it promulgated rules to implement the ADAMHA Amendments. Initially, to be sure, HHS had contemplated an active role for itself in shaping state legislative and enforcement efforts. It proposed a requirement that States put in place "well-designed procedures" to ensure compliance with state access laws setting the minimum age at 18. 58 Fed. Reg. 45,156, 45,173 (1993) (proposed 45 C.F.R. § 96.130(c)(2)). Examples included vending machine restrictions and licensing requirements. *Id.* This proposal provoked comments that HHS was deviating from Congress' intent: "Many commenters" informed HHS that the requirement that States adopt particular "well-designed procedures" exceeded "the scope of the statute, congressional intent and Department discretion under the statute." 61 Fed. Reg. 1492, 1495 (1996).

After considering the comments, HHS adopted final regulations that reflected the force of these criticisms. 61 Fed. Reg. 1508 (codified at 45 C.F.R. §§ 96.123, 96.130). In describing its final regulations, HHS repeatedly emphasized the importance of the States' flexibility in determining the design of their own access restrictions, *id.* at 1493-96, and eliminated the requirement for "well-designed procedures," *id.* at 1495. For example, HHS stated:

> Bans and restrictions on vending machines and locking devices are viable options for States to consider in reducing tobacco sales to minors, but again,

under this regulation the Department intends to allow States flexibility in the strategies they use to enforce tobacco control laws.

Id. at 1496. Similarly, HHS considered and rejected suggestions that it require other specific enforcement mechanisms, including banning self-service displays and sampling. *Id.* at 1500-01. When reminded of congressional intent that it preserve state autonomy, HHS declined to impose its will on the States.

II. FDA'S REGULATIONS USURP STATE AUTHORITY PRESERVED BY CONGRESS.

A. FDA's Exercise of Jurisdiction Repudiates Congress and Its Plan to Control Tobacco Access by Minors.

At the very outset of its tobacco rulemaking, by contrast, FDA questioned the balance struck by Congress in the ADAMHA Amendments, and argued that only direct federal involvement would achieve the reduction in tobacco access that Congress believed could be achieved through the ADAMHA Amendments. FDA noted that, pursuant to the Amendments, the Substance Abuse and Mental Health Services Administration ("SAMHSA") had "proposed a program of State-operated enforcement activities that would restrict the sale or distribution of tobacco products to individuals under 18 years of age." 60 Fed. Reg. 41,314, 41,362 (1995).[9] FDA voiced its support for the "basic objectives" of this program mandated by Congress, but it was FDA's view that the "full achievement" of Congress' objectives demanded "a broad arsenal of controls"—namely, FDA's proposed regulations. *Id.*

[9] The Amendments, enacted in 1992, established SAMHSA as an agency of the Public Health Service within HHS. 42 U.S.C. § 290aa(a).

In the preamble to its final tobacco regulations, FDA went even further: it "disagreed that regulation of tobacco sales or decisions about eligibility and maturity are traditional State functions[,]" and it omitted any description of the historical background of state regulation, which Congress intended to preserve. *See* 61 Fed. Reg. 44,396, 44,429 (1996). Thus, after Congress chose state autonomy instead of federal command and control for regulating tobacco access, FDA imposed a program of nationally uniform tobacco-access regulations that conflicts directly with congressional intent as expressed in the ADAMHA Amendments.[10]

FDA's rule broadens significantly the scope of its enforcement responsibilities. By its own count, FDA's regulations cover over 500,000 retail establishments throughout the United States. 61 Fed. Reg. 44,578. Every failure to conform to FDA's mandate is a federal offense, 21 C.F.R. § 897.1(b); 21 U.S.C. §§ 331(b), (k), punishable by federal prosecution, *id.* § 333(a)(1), or by civil penalty imposed by FDA and reviewable in the federal courts of appeals, *id.* § 333(f). If FDA's enforce-

[10] FDA also disagreed with its parent agency's view that the ADAMHA Amendments are adequate to achieve their purpose. HHS had stated that the flexible approach agreed upon by Congress should work: "Eliminating virtually all sales to minors does not even present particularly difficult enforcement problems. It simply requires workable procedures [by the States] which create swift and sure sanctions for violations, with minimal cost or inconvenience to retailers and adult customers." 58 Fed. Reg. 45,165. HHS had estimated that the program under the ADAMHA Amendments could reduce sales of cigarettes to persons under age 18 as much as two-thirds within three years. *Id.* at 45,158. That estimate was published before FDA decided to regulate tobacco products. HHS reduced its estimate after FDA announced its tobacco regulations, when it became expedient for HHS to support the asserted need for, and predicted benefit of, FDA's competing program. *See* 61 Fed. Reg. 1501-02.

ment history is any guide, it is only a matter of time before corner stores contesting civil penalties appear in federal courts across the land. *Cf. United States v. Park*, 421 U.S. 658, 665-66 (1975) (five-count conviction for food adulteration in violation of the FDCA, fine of $50 for each count).

B. FDA's Regulations Preempt State Statutes and Local Ordinances.

In the exercise of their traditional police powers, state and local governments have adopted a wide variety of tobacco-access restrictions, none of which has ever been disturbed by any federal tobacco-specific statute. The FDCA, however, preempts every state or local enactment that addresses the subject matter of FDA's regulations with respect to a device, if that enactment differs from or adds to the regulations:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device. . . .

21 U.S.C. § 360k(a)(1). Under this section, FDA requirements do not establish thresholds that States are free to exceed or constraints that States are free to relax. Rather, the preemption section of the FDCA reflects Congress' unequivocal grant of plenary regulatory control over medical devices to FDA.

FDA concedes that its regulations preempt outright a variety of state and local tobacco-access laws—including statutes requiring a higher age of eligibility for purchasing tobacco products, as well as ordinances imposing tougher restrictions on self-service displays, vending machines, or

identification requirements. 61 Fed. Reg. 44,548-49. FDA contends, however, that "only a limited number of State and local requirements are preempted and even those may qualify for exemption from preemption under [21 U.S.C. § 360k(b)]." *Id.* at 44,548. The reality is that FDA's regulations automatically preempt hundreds of state and local tobacco-access laws. Among the laws are the following:

1. *Age Requirements.* Alabama, Alaska, and Utah prohibit the sale of cigarettes to anyone under age 19, Addendum, Vol. 1, Tab 1, in contrast to FDA's regulations, which set the age at 18. 21 C.F.R. § 897.14(a); 61 Fed. Reg. 44,396 (providing compliance date of Feb. 28, 1997). In the fall of 1996, the three States sought exemptions from preemption. *See* 62 Fed. Reg. 7390, 7391-94 (1997) (Docket No. 96N-0249). FDA agreed the laws were preempted and granted the exemptions effective December 29, 1997, more than a year after the States had applied for them. 62 Fed. Reg. 63,271, 63,274 (1997) (codified at 21 C.F.R. §§ 808.51, 808.52, 808.94). Thus, from February 28, 1997 until December 29, 1997, FDA preempted statutes in Alabama, Alaska, and Utah, and thereby *lowered* the legal tobacco-purchasing age in those States from 19 to 18.

2. *Absolute Bans on Vending Machines and Self-Service Displays.* At least 177 local ordinances completely ban tobacco sales from vending machines or self-service displays, or both. *See* Addendum, Vols. 1-3, Tab 2. FDA's regulations allow vending machines and self-service displays in adult-only venues. *See* 21 C.F.R. § 897.16(c)(2)(ii). FDA's regulations preempt [11] these

[11] More properly, "will preempt," if the district court's stay is dissolved. Two provisions of FDA's tobacco regulations became effective on February 28, 1997—the age restriction and the pur-

ordinances and revive marketing methods these governments had prohibited.

3. *Location Restrictions on Vending Machines and Self-Service Displays.* At least 17 local ordinances restrict the location of vending machines or self-service displays, or both, within adult-only venues. *See* Addendum, Vol. 4, Tab 3. FDA's regulations impose no location restrictions within such venues. *See* 21 C.F.R. § 897.16(c)(2)(ii). FDA's regulations preempt these ordinances and relax controls that these localities adopted.

4. *Age Verification Requirements.* At least one state statute and one local ordinance require that retailers verify age with a government-issued identification card. *See* Addendum, Vol. 4, Tab 4. FDA's regulations do not require a government-issued identification card. *See* 21 C.F.R. § 897.14(b)(1).[12] FDA's regulations preempt these requirements and dilute the proof-of-age standard in these jurisdictions.

In addition to preempting state or local laws that prohibit too much, FDA's tobacco regulations preempt or nullify laws that embody different, competing solutions. Approaches to access restriction that States and localities may no longer employ include the following:

5. *Lockout Devices on Vending Machines and Self-Service Displays.* At least 17 localities require that vending machines or self-service displays, or both, be equipped

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chaser-age-verification requirement. 21 C.F.R. § 897.14(a)-(b). Although the district court stayed regulations that had not gone into effect at the time of its ruling in April, 1997, it permitted the continued implementation of the provisions that had taken effect. Appendix To Petition For a Writ of Certiorari ("Pet. App.") 135a.

12 FDA stated that "the final rule does not require . . . a Federal, State, or local government identification card." 61 Fed. Reg. 44,438-39.

with lockout devices controlled by the retailer. *See* Addendum, Vol. 4, Tab 5. FDA's regulations restrict vending machines and self-service displays to adult-only venues. 21 C.F.R. § 897.16(c)(2)(ii). FDA's regulations preempt or nullify these localities' determinations that lockout devices adequately control access to tobacco products from vending machines and self-service displays.

6. *Line-of-Sight Restrictions for Vending Machines and Self-Service Displays.* At least five States and 35 localities require that vending machines or self-service displays, or both, be placed in the line of sight of employees in retail establishments. *See* Addendum, Vol. 5, Tab. 6. FDA's regulations restrict vending machines and self-service displays to adult-only venues. FDA's regulations preempt or nullify these localities' determinations that line-of-sight restrictions are an effective way to control access to tobacco products from vending machines and self-service displays.

7. *Sampling Restrictions.* At least 48 States prohibit the provision of free samples of tobacco products to minors, but not to adults; and several localities restrict where sampling can be done. *See* Addendum, Vol. 6, Tab 7. FDA's complete prohibition on free samples, 21 C.F.R. § 897.16(d), preempts or nullifies these state laws.

So far, state and local governments have filed over 300 applications with FDA seeking exemptions from preemption. *See* Index to Docket No. 96N-0249 listing applications (Aug. 31, 1999). The continued viability of these laws now depends on whatever dispensations may result from future FDA rulemakings.

C. There is Inherent Conflict Between the ADAMHA Amendments and FDA's Assertion of Jurisdiction Over Tobacco Products.

By enacting the ADAMHA Amendments, Congress acknowledged that States and local governments are the proper source of tobacco-access restrictions. Congress did not offer States the choice of regulating retailers according to federal standards or having state law preempted by federal regulation. Nor did it enact a detailed regulatory scheme of its own, around which the States might legislate. Nor did it pass legislation preempting any state law that regulates retail access to tobacco products. Rather, Congress encouraged the States to establish age 18 as the legal age for purchasing tobacco products, and encouraged the States to enforce their own legislation in a manner of their choosing. It remained the responsibility of the States to reduce minors' ability to buy tobacco products. FDA's "broad arsenal of controls" now stands as an obstacle to the accomplishment of Congress' purposes in enacting the ADAMHA Amendments.

The Government insists there is no "inherent or irreconcilable conflict" between the ADAMHA Amendments and FDA's assertion of jurisdiction over tobacco products under the FDCA, because States can seek permission from FDA to enforce their otherwise preempted laws. Pet. Br. 48. But as the court of appeals found, "the possibility of a discretionary exemption does not take away the inherent conflict[.]" Pet. App. 51a. That States are forced to petition [13] FDA to spare congressionally induced legislation, and then await the outcome of another FDA rulemaking, demonstrates the severity of this conflict.

The jurisdictional grant asserted by the Secretary of HHS and the Commissioner of Food and Drugs pursuant

[13] 21 C.F.R. §§ 808.1, *et seq.*

to the FDCA is incompatible with the tobacco-access control plan Congress enacted in the ADAMHA Amendments. In the provisions of the Amendments dealing specifically with tobacco, Congress refused to disturb state authority and discretion to determine how best to achieve the goal of tobacco-access reduction. The Government's argument, Pet. Br. 48, that the ADAMHA Amendments do not protect all state regulations of tobacco misses the point that the Amendments were intended to preserve the States' autonomy to regulate tobacco access. FDA has promulgated a rule that takes that autonomy away.

The Administrative Procedure Act ("APA") provides that a reviewing court "shall hold unlawful and set aside agency action . . . found to be in excess of statutory jurisdiction, authority, or limitations, or short of statutory right[.]" 5 U.S.C. § 706(2)(C). The inherent inconsistency between the two competing programs is apparent from a plain reading of the operative provisions of the ADAMHA Amendments and the FDA regulations.

Congress, however, did not leave the resolution of such inconsistencies to the general provisions of the APA. In drafting the ADAMHA Amendments, Congress went out of its way expressly to preclude the adoption of administrative regulations that would conflict with its legislative policy:

> Any rule or regulation of the Department of Health and Human Services that is inconsistent with the amendments made by this Act shall not have any legal effect. . . .

106 Stat. 410. This provision expresses a congressional determination that the basic policy set forth in the ADAMHA Amendments shall be the only federal policy relating to the retail sale of tobacco products, and that the substantive restrictions on retail sales to per-

sons under age 18 shall be designed and enforced by the States. The Amendments make clear the limits of federal jurisdiction over retail sales of tobacco. Congress left no room for an agency within HHS to disagree. FDA's assumption of authority to decide which state and local restrictions will survive, and which will not, should be rejected.

III. FDA's REGULATIONS IMPERMISSIBLY IMPOSE FUNDING CONDITIONS NOT APPROVED BY CONGRESS.

That FDA is usurping jurisdiction in an area Congress left to the States becomes even more evident when the ADAMHA Amendments are considered in light of their constitutional basis—the spending power in Article I, § 8, cl. 1. The Amendments condition the availability of federal funds on the States taking certain actions. There is no doubt that Congress, under its spending power, may condition the receipt of federal funds on certain state action. *King v. Smith*, 392 U.S. 309, 333 n.34 (1968). Congress, however, must make these conditions explicit and unambiguous, so that States understand the bargain they have made when they accept the terms of the "contract." *Pennhurst State School & Hospital v. Halderman*, 451 U.S. 1, 17 (1981). Once the conditions have been set, and the States have accepted those terms, a federal agency does not have the authority to alter the obligations that States must undertake in order to receive the funds. This Court has held:

> Though Congress' power to legislate under the spending power is broad, it does not include surprising participating States with post acceptance or "retroactive" conditions.

Id. at 25; *see also King*, 392 U.S. at 333 n.34 (HEW cannot approve a change in conditions "inconsistent with the controlling federal statute").

The ADAMHA Amendments offered the States an incentive to reduce the sales of tobacco products to individuals under age 18. The Amendments made the conditions of that offer explicit and unambiguous. So far, every State has accepted those conditions and qualified for the full SAPT block grant promised by Congress.[14]

FDA's regulations impermissibly impose on the States further obligations that burden the administration of their programs and interfere with their ability to meet their goals and obtain their promised share of funding under the Amendments. A State must now seek permission from FDA to do what Congress induced it to do, and must bear the risk that FDA will delay or deny its dispensation. For example, numerous local governments have determined that too many underage sales result from vending machines.[15] As a result, city councils passed ordinances banning outright the sale of tobacco products in vending machines. *See* p. 15, *supra*. But under FDA's regulations, a local government's new vending-machine law cannot be enforced: it is preempted because it is different from FDA's vending-machine regulation, which permits vending machines "in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time." 21 C.R.F. § 897.16

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[14] SAMHSA reported to Congress that "[a]ll States are in material compliance with the [ADAMHA Amendments]. They have laws prohibiting the sale or distribution of tobacco to minors, and they are enforcing those laws . . . . All States expect to achieve the goal of a maximum sales-to-minors rate of 20 percent by Federal Fiscal Year (FFY) 2003." SAMHSA, *Synar Regulation Implementation FY 97 State Compliance* 1 (undated).

[15] In a "model law," HHS recommended the States adopt a measure prohibiting tobacco sales through vending machines, presumably because HHS also thought such a prohibition would be effective. 58 Fed. Reg. 45,165 (Section 5(b) of the Model Sale of Tobacco Products to Minors Control Act).

(c)(2)(ii). State and local governments must apply to FDA for an exemption, and, in the interim, either select another approach that will achieve the necessary reduction in tobacco sales to minors or put its SAPT block grant at risk.

The experience of Alaska illustrates the damage that FDCA preemption can do when applied to state access-restriction programs. In its exemption application filed with FDA in the fall of 1996, Alaska voiced its "great concern" with the higher percentage of its high school students who became frequent cigarette smokers compared with the general U.S. high school population, and stated that restricting sales to purchasers 19 years and older "severely limit[ed] legal access of cigarettes to high school students." State of Alaska's Application for Exemption from 21 C.F.R. § 897.14(a) (Docket No. 96N-0249) (Nov. 27, 1996) 2, 3.[16] Alaska insisted that restriction "must continue to remain an overall part of the state's tobacco use deterrent efforts." *Id.* at 4. Nonetheless, for 10 months, FDA took it away (and took it away from Alabama and Utah). *See* p. 15, *supra*. Depriving States of their preferred approaches to access reduction is not a result Congress intended when it passed the ADAMHA Amendments. Forcing States to choose other approaches, or to risk the loss of ADAMHA Amendment funds, is prohibited by *Pennhurst*.

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[16] That Alaska and other States believe a higher minimum age sales law is an effective means to reduce cigarette consumption among adolescents could not have surprised HHS, for it recommended that States adopt a measure setting the age for tobacco sales at 19. 58 Fed. Reg. 45,165 (Section 5(a) of the Model Sale of Tobacco Products to Minors Control Act).

CONCLUSION

Accordingly, the Court should affirm the judgment of the court of appeals.

Respectfully submitted,

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